

Food and Drug Administration, HHS

§ 520.300c

(iii) A veterinarian should be consulted before using in severely debilitated dogs.¹

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 39858, Aug. 29, 1975; 44 FR 10059, Feb. 16, 1979; 54 FR 38515, Sept. 19, 1989; 55 FR 24556, June 18, 1990; 64 FR 15684, Apr. 1, 1999; 70 FR 50182, Aug. 26, 2005]

§ 520.300 Cambendazole oral dosage forms.

§ 520.300a Cambendazole suspension.

(a) *Specifications.* Each fluid ounce contains 0.9 gram of cambendazole.

(b) *Sponsor.* No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in horses for the control of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); small strongyles (*Trichonema*, *Poteriostomum*, *Cylicobrachytus*, *Craterostomum*, *Oesophagodontus*); roundworms (*Parascaris*); pinworms (*Oxyuris*); and threadworms (*Strongyloides*).

(2) It is administered by stomach tube or as a drench at a dose of 0.9 gram of cambendazole per 100 pounds of body weight (20 milligrams per kilogram).

(3) For animals maintained on premises where reinfection is likely to occur, re-treatments may be necessary. For most effective results, re-treat in 6 to 8 weeks.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.

(6) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975. Redesignated at 41 FR 1276, Jan. 7, 1976, and amended at 42 FR 3838, Jan. 21, 1977; 62 FR 63270, Nov. 28, 1997]

§ 520.300b Cambendazole pellets.

(a) *Specifications.* The drug is in feed pellets containing 5.3 percent cambendazole.

(b) *Sponsor.* No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in horses for the control of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); small strongyles (*Trichonema*, *Poteriostomum*,

Cylicobrachytus, *Craterostomum*, *Oesophagodontus*); roundworms (*Parascaris*); pinworms (*Oxyuris*); and threadworms (*Strongyloides*).

(2) Administer 20 milligrams cambendazole per kilogram body weight (6 ounces per 1,000 pounds) by mixing with normal grain ration given at one feeding. Doses for individual horses should be mixed and fed separately to assure that each horse will consume the correct amount.

(3) For animals maintained on premises where reinfection is likely to occur, re-treatments may be necessary. For most effective results, re-treat in 6 to 8 weeks.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.

(6) Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[41 FR 1276, Jan. 7, 1976, as amended at 42 FR 3838, Jan. 21, 1977; 62 FR 63270, Nov. 28, 1997]

§ 520.300c Cambendazole paste.

(a) *Specifications.* The drug is a paste containing 45 percent cambendazole.

(b) *Sponsor.* No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) It is used in horses for the control of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); small strongyles (*Trichonema*, *Poteriostomum*, *Cylicobrachytus*, *Craterostomum*, *Oesophagodontus*); roundworms (*Parascaris*); pinworms (*Oxyuris*); and threadworms (*Strongyloides*).

(2) Administer 20 milligrams cambendazole per kilogram body weight (5 grams per 550 pounds (250 kilograms)) by depositing the paste on the back of the tongue using a dosing gun.

(3) For animals maintained on premises where reinfection is likely to occur, re-treatments may be necessary. For most effective results, re-treat in 6 to 8 weeks.

(4) Not for use in horses intended for food.

(5) Caution: Do not administer to pregnant mares during first 3 months of pregnancy.

§ 520.309

(6) Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[41 FR 1276, Jan. 7, 1976, as amended at 42 FR 3838, Jan. 21, 1977; 62 FR 63270, Nov. 28, 1997]

§ 520.309 Carprofen.

(a) *Specifications.* (1) Each caplet contains 25, 75, or 100 milligrams (mg) carprofen.

(2) Each chewable tablet contains 25, 75, or 100 mg carprofen.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) No. 000069 for use of products described in paragraph (a) of this section as in paragraph (d) of this section.

(2) Nos. 000115, 055529, and 062250 for use of product described in paragraph (a)(1) as in paragraph (d) of this section.

(c) [Reserved]

(d) *Conditions of use in dogs*—(1) *Amount.* 2 mg per pound (lb) of body weight once daily or 1 mg/lb twice daily. For the control of postoperative pain, administer approximately 2 hours before the procedure.

(2) *Indications for use.* For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries.

(3) *Limitations.* Federal Law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 66581, Dec. 18, 1996, as amended at 64 FR 32181, June 16, 1999; 66 FR 63165, Dec. 5, 2001; 67 FR 6866, Feb. 14, 2002; 67 FR 65038, Oct. 23, 2002; 67 FR 65697, Oct. 28, 2002; 70 FR 30626, May 27, 2005; 71 FR 51995, Sept. 1, 2006; 72 FR 68478, Dec. 5, 2007; 74 FR 21768, May 11, 2009]

§ 520.310 Caramiphen ethanedisulfonate and ammonium chloride tablets.

(a) *Specifications.* Each tablet contains 10 milligrams of 5st caramiphen ethanedisulfonate and 80 milligrams of ammonium chloride.¹

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

21 CFR Ch. I (4–1–12 Edition)

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* One tablet per 15 to 30 pounds of body weight every 4 to 6 hours.¹

(2) *Indications for use.* For relief of cough.¹

[43 FR 55385, Nov. 28, 1978]

§ 520.312 Carnidazole tablets.

(a) *Specifications.* Each tablet contains 10 milligrams of carnidazole.

(b) *Sponsor.* See 053923 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Adult pigeons: 1 tablet (10 milligrams); newly weaned pigeons: ½ tablet (5 milligrams).

(2) *Indications for use.* For treating trichomoniasis (canker) in ornamental and homing pigeons.

(3) *Limitations.* Not for use in pigeons intended for human food. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism or when severely ill birds do not respond to treatment.

[54 FR 32336, Aug. 7, 1989]

§ 520.314 Cefadroxil.

(a) *Specifications.*—(1) Each tablet contains 50, 100, or 200 milligrams (mg) or 1 gram of cefadroxil.

(2) Each milliliter of suspension constituted from powder contains 50 mg of cefadroxil.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*—(i) *Dogs.* Administer 10 mg per pound (lb) body weight twice daily orally.

(ii) *Cats.* Administer 10 mg/lb body weight once daily orally.

(2) *Indications for use*—(i) *Dogs.* For the treatment of skin and soft tissue infections including cellulitis, pyoderma, dermatitis, wound infections, and abscesses due to susceptible strains of *Staphylococcus aureus*. For the treatment of genitourinary tract infections (cystitis) due to susceptible strains of *Escherichia coli*, *Proteus mirabilis*, and *S. aureus*.

(ii) *Cats.* For the treatment of skin and soft tissue infections including abscesses, wound infections, cellulitis, and dermatitis caused by susceptible